

REMARKS

A Request for Continued Examination (RCE) and requisite fee have been submitted along with this Response. Since the Office Action was made final, the RCE was filed so that the Examiner would enter and consider the amendments and remarks of the present Response.

Status of All of the Claims

Below is the status of the claims in this application.

1. Claim(s) pending: 33-42 and 48-63.
2. Claim(s) canceled: 1-32 and 43-47.
3. Claim(s) added: 48-63.
4. Claims withdrawn from consideration but not canceled: 35, 36, 42, 48, and 57.

It is believed that the above-identified new and amended claims are supported by the application as originally filed. For example, support for the amendments to claims 33 and 40 can be at least found at pages 10 and 13-14 of the specification and FIGS. 11-12 of the drawings. In another example, support for claims 48 and 57 can be at least found at pages 14-15 of the specification and FIGS. 13-16 of the drawings. Support for new claims 49 and 58 can be at least found at pages 10 and 13-14 of the specification and FIGS. 11-12 of the drawings. As still yet another example, support for claims 50-54 and 59-63 can be at least found on pages 9 and 12-14 of the specification as well as in FIGS. 11-12 of the drawings.

Interview

The Applicants first wish to thank Examiner Hoekstra for the telephonic interview of June 13, 2007 concerning the above-identified application. At the interview, proposed claim amendments similar to the amendments made above to claims 33 and 40 were presented. These amendments were discussed in view of the cited references, in particular WO 98/24366 A2 to Abbott. The Examiner provided some suggestions to further structurally distinguish the claims from Abbott, and the amendments in this response have incorporated those suggestions as well as other refinements. While recognizing that additional searching by the Examiner might be required, based on the positive feedback from the Examiner at the interview, it is believed that the claims as currently amended are in condition for allowance. In accordance with the

discussion at the interview, an RCE has been submitted with this response in order to have the amendments and remarks entered into the case. The substantive remarks presented at the interview have been again provided below.

Independent Claim 33

As discussed at the interview, claim 33 has been amended to remove the lancing device feature which is now recited in dependent claim 48. The Examiner indicated that this amendment would make claim 33 read on the elected species, and consequently, claim 33 would be considered for examination purposes. In accordance with the Examiner's suggestions, further structural features to the sampling passageway as well other features are now recited in claim 33 that distinguish it from the cited references, such as WO 98/24366 to Abbott Laboratories (hereinafter referred to as "Abbott"). For example, at the interview, the Examiner indicated that further structurally specifying the capillary passageway would likely distinguish claim 33 from Abbott. Consequently, claim 33 has been amended to recite "a sampling passageway with an inlet opening that is remotely located from the test area, the sampling passageway being sized and configured to draw the body fluid via capillary action, the sampling passageway extending from the inlet opening to the test area for transporting the body fluid from the incision to the test area via capillary action."

Claim 33 has been further refined to recite "a test strip configured for loading into a lancing device to analyze body fluid from an incision created by the lancing device" and "wherein the test strip has a strip shape" to highlight the distinctions between the recited test strip and the lancing assembly 16 or nosepieces of Abbott. Even if claim 33 is construed broadly, no one of ordinary skill in the art would reasonably consider the lancing assembly 16 or nosepieces 1000, 1200, 3000 in Abbott to be test strips because they do not have a strip shape. No one skilled in the art would in their right mind find the nosepieces in Abbott to have a long and narrow shape such that they have a strip shape. Instead, one skilled in the art would consider the elements (1100, etc.) of FIGS. 21-27 of Abbott as corresponding to a test strip. However, the elements 1100 of FIGS. 21-27 in Abbott clearly lack "a sealing member projecting outwardly from the bottom surface of the test strip proximal the inlet opening and positioned to seal with the skin when the test strip is pressed against the skin to retain the body fluid at the inlet opening" as is recited in claim 33. As such, Abbott fails to disclose the test strip with the sealing

member as recited in claim 33. As mentioned before, by having the sealing member on the test strip, cross contamination can be minimized because the sealing member, which can contact blood during sampling, is disposed of with the test strip. To highlight this feature, claim 33 recites “wherein the test strip with the sealing member is configured to be unloaded from the lancing device as a single disposable unit.” Considering that Abbott does not disclose the test strip with the sealing member as recited, claim 33 is not anticipated by Abbott, and given that the other references do not likewise disclose this missing feature, it is submitted that claim 33 is not obvious in view of the references of record. Based on the Examiner’s positive comments regarding claim 33 as well as the remarks made above, it is submitted that claim 33 and its dependent claims are in condition for allowance.

Claim 33’s Dependent Claims

In addition to the reasons given above for independent claim 33, additional reasons support the allowance of its dependent claims. For example, Abbott does not disclose, either expressly or inherently, “the test area includes an opening that opens at the top surface of the test strip to permit reflectance of light for optical analysis” as is recited in dependent claim 49. As discussed and apparently acknowledged by the Examiner during the interview, Abbott does not disclose a test strip with the particular characteristic of the test area opening at the top surface of the test strip. The other references of record fail to remedy this missing feature. For these and other reasons, it is submitted that dependent claim 49 is in condition for allowance.

As another example, Abbott does not disclose “at least a portion of the top surface is hydrophobic to resist flow of the body fluid along the top surface” as is recited in dependent claim 50. The other references of record likewise do not disclose this feature as well. For these and other reasons, dependent claim 50 is in condition for allowance.

Independent Claim 40

Claim 40 has also been amended to remove the lancing device feature which is now recited in dependent claim 57. At the interview, the Examiner indicated that if claim 40 was amended in such a manner, it would be considered for examination purposes. In accordance with the Examiner’s suggestion, further structural features to the sampling passageway as well other features are now recited in claim 40 that distinguish it from the cited references, such as

Abbott. Consistent with the suggestions made at the interview, claim 40 has been amended to structurally recite features of the capillary passageway that further distinguish it from Abbott. To further clarify that the recited test strip is indeed a test strip and not some other component, claim 40 specifies that “a test strip configured for loading into a lancing device to analyze body fluid from an incision created by the lancing device” and “wherein the test strip has a strip shape.” In view of these features, even if claim 40 was broadly construed, no one of ordinary skill in the art would have reasonably concluded that the lancing assembly 16 or nosepieces 1000, 1200, 3000 in Abbott correspond to the recited test strips. The lancing assembly and nosepieces clearly do not have a strip shape. Likewise, the elements 1100 of FIGS. 21-27 in Abbott cannot correspond to the recited test strip because they lack “a recessed surface extending between the inlet opening and the bottom surface to inhibit contact of the body fluid on the skin with the bottom surface of the test strip” as is recited in claim 40. To emphasize the benefit of having the recessed surface on the test strip rather than on other components, such as the lancing device, claim 40 further recites “wherein the test strip with the recessed surface is configured to be unloaded from the lancing device as a single disposable unit. As was brought to the Examiner’s attention during the interview, having the recessed surface on the test strip reduces the risk of cross contamination of blood (or other body fluids) between patients because the test strips are disposed of after each test. Considering the other references of record do not disclose such a recessed surface on a test strip, claim 40 is both novel and not obvious in view of the references of record. For these and other reasons, it is submitted that claim 40 and its dependent claims are allowable over the references of record.

Claim 40’s Dependent Claims

In addition to the reasons given above for independent claim 40, additional reasons support the allowance of its dependent claims. For example, Abbott does not disclose or suggest “the test area includes an opening that opens at the top surface of the test strip to permit reflectance of light for optical analysis” as is recited in dependent claim 58. As recognized by the Examiner during the interview, Abbott does not disclose a test strip with the particular characteristic of the test area opening at the top surface of the test strip. Likewise, the other references of record fail to remedy this missing feature. For these and other reasons, it is submitted that dependent claim 58 is in condition for allowance.

As another example, Abbott does not disclose “at least a portion of the top surface is hydrophobic to resist flow of the body fluid along the top surface” as is recited in dependent claim 59. The other references of record likewise do not disclose this feature as well. For these and other reasons, dependent claim 59 is in condition for allowance.

Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion.

In view of the above amendments and remarks, it is submitted that the present application is now in condition for allowance, and the Examiner is requested to pass the case to issue. If the Examiner should have any comments or suggestions to help speed the prosecution of this application, the Examiner is requested to contact the undersigned representative by telephone.

Respectfully submitted,

By /Charles P. Schmal #45,082/
Charles P. Schmal, Reg. No. 45082
Woodard, Emhardt, Moriarty, McNett & Henry LLP
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
(317) 634-3456